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RAISE PLUS TASK ORDER: SHORT-TERM TECHNICAL ASSISTANCE IN BIOTECHNOLOGY

ANNUAL PROGRESS REPORT: OCTOBER 2008–SEPTEMBER 2009

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RAISE PLUS TASK ORDER: SHORT-TERM TECHNICAL ASSISTANCE IN BIOTECHNOLOGY

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INTRODUCTION

Under the Rural and Agricultural Incomes with a Sustainable Environment (RAISE PLUS) indefinite quantity contract, the U.S. Agency for International Development (USAID) Office of Economic Growth, Agriculture and Trade (EGAT) has launched a three-year \$3 million task order titled Short-Term Technical Assistance in Biotechnology. The purpose of the task order is to complement longer-term biotechnology-related development efforts with short-term technical assistance in service of the EGAT/Environment and Science Policy/International Research and Biotechnology Team (EGAT/ESP/IRB), USAID field missions, and USAID client countries. The scope of activities covered by the task order reflects the need for rapid and targeted technical assistance to address the requests of client countries, as well as for a mechanism for EGAT/ESP/IRB to provide technical leadership and support to other USAID units and other U.S. Government agencies. RAISE PLUS services are provided by a consortium of partners consisting of DAI, Michigan State University, Agriculture and Biotechnology Strategies (AGBIOS), and the Donald Danforth Plant Science Center.

This report encompasses activities conducted under the RAISE PLUS Short-Term Technical Assistance in Biotechnology task order during the fourth year of the contract (October 2008–September 2009). The task order was supposed to end on September 30, 2008, but received a no-cost extension for two years, with a new end date of September 29, 2010. The reasons for the extension included the stepwise nature of the activity, environmental circumstances, political difficulties with the Association of Southeast Asian Nations (ASEAN) hampering progress, and activities with long cycles (e.g., field trials, policy reform). For an overview of all activities in relation to the contract deliverables, please see Annex A.

Specific objectives and tasks (with contract reference number):

- Bio-engineered Cotton (Bt Cotton) in Africa (A.3.2)
- Regulatory Assistance (A.3.3)
- Technical Assistance to Food Aid Recipient Countries (A.3.4)
- Biosafety Policy and Regulatory Assistance (A.3.5)
- Technical Conferences (A.3.6)
- Trade Capacity Building (A.3.7)

COMPLETED ACTIVITIES

YEAR 1: OCTOBER 2005–SEPTEMBER 2006 (RECAP)

BIO-ENGINEERED COTTON IN AFRICA (A.3.2)

Activity 2: Entomology Training in Bamako, Mali, December 2005

Training in entomology was conducted in Bamako, Mali, in December 2005. Four participants, from Benin, Burkina Faso, Chad, and Mali, participated, along with one participant from Tuskegee University, USA. DAI provided logistical support by purchasing and providing air tickets for the five participants.

REGULATORY ASSISTANCE (A.3.3)

Activity 5: INSAH Technical Support 2

Under this activity, DAI's implementing partner AGBIOS reviewed and provided comments on revised biosafety and seed conventions; translated revised biosafety and seed conventions from French into English; provided technical assistance to develop a workplan for the six-month period from April through September 2006; and assisted with candidate interviews to staff a regional biosafety office.

Activity 9.2: Technical Assistance to Burkina Faso

Dr. MacKenzie of AGBIOS participated in meetings with Dr. Lompo (National Biosecurity Agency) and Dr. Ouedraogo (INERA) to develop a workplan for providing technical assistance to strengthen capacity in environmental risk assessment and risk management for field trials and commercial release of transgenic products, particularly Bt cotton. His actions included meetings with Dr. Ouedraogo and Dr. Lompo regarding joint INERA-NBA cooperation in organizing a cotton producers' workshop in Bobo Dioulasso, Burkina Faso, in the fall of 2006; meetings with Pr. Alassane Sere (Burkina Biotech Association) and Dr. Ouedraogo (INERA) on possible biotechnology communications activities in Burkina Faso; and meetings with CORAF to finalize the terms of reference for the biotechnology coordinator position and to discuss their involvement in the cotton producers' workshop.

Activity 11: INSAH Convention Translations

DAI arranged for the translation and review of *Final Convention Biosecuritaire*, *Final Convention Reglement Semences*, and *Final Structure et Fonct CRC*.

TECHNICAL ASSISTANCE TO FOOD AID RECIPIENT COUNTRIES (A.3.4)

No activities under A.3.4 during Year 1.

BIOSAFETY POLICY AND REGULATORY ASSISTANCE (A.3.5)

Activity 3: INSAH/CILSS Tech Support: Regional Biosafety Framework Development, January 17–19

USAID is supporting work by INSAH to initiate a project to create a regional biosafety framework for West Africa. INSAH requested further support specifically related to an INSAH/CILSS meeting to

validate the “Framework Convention Introducing a Common Biosafety Regulation in the CILS countries” and the “Framework Convention Instituting Common Regulations for Conventional and Transgenic Seeds in the CILS Area” in Niamey, Niger, January 17–19, 2006. This request was specifically to support the translation from French into English of three draft documents (two draft conventions and an elaboration of a proposed implementing committee structure), review of the draft documents, and participation in the January workshop of a technical resource person. Dr. Donald MacKenzie, Vice President, AGBIOS, attended these two meetings. Significant progress was made on amending both framework conventions and in confirming the desire for a regional approach to biosafety and seeds regulation.

The amended biosafety convention has included new articles dealing with foods derived from genetically modified organisms (GMOs) and public access to information, and has made clearer distinctions between “contained,” “confined,” and “unconfined” activities involving GMOs. The revised convention also better describes the role of the Regional Consultative Committee and the division of decision-making responsibility between national competent authorities and the regional body. Once the convention is adopted by the Council of Ministers, there will need to be additional work on developing specific protocols under the convention to deal with risk assessment criteria and administrative requirements for different levels of activity (e.g., confined field trials vs. unconfined, or general, release) and with food safety.

Activity 4: Translation of ECOWAS Action Plan for Biotechnology and Biosafety Strategy Development

USAID supported the development of a regional strategy for biotechnology and biosafety in West Africa through a series of workshops and meetings led by CORAF that culminated in the Economic Community of West African States (ECOWAS) Ministerial Conference on Agricultural Biotechnology, held in Bamako, Mali, in June, 2005. The ministers endorsed several overarching recommendations that provided general direction for such a strategy, and recommended that an action plan be prepared to detail the way forward. ECOWAS convened a meeting in October 2005 in Abuja, Nigeria, to discuss the elements of the action plan and assigned the further development of the action plan to two consultants, who recently completed a draft that is partially in English and partially in French. This activity translated the draft “Action Plan for the Development of Biotechnology and Biosafety in Countries of the ECOWAS 2006–2010” into two complete versions, one in English, one in French. AGBIOS completed the assignment and the required deliverable before January 16, 2006.

Activity 8.1 and Activity 8.2: RDMA Policy Support

Mrs. Koch of AGBIOS participated in the ASEAN-United States Roundtable on Agricultural Biotechnology Policy and Strategy, April 4–5, 2006, in Bangkok, Thailand. She undertook a scan of ASEAN sub-regional and bilateral agriculture biotechnology-related programs in Southeast Asia and assisted RDM/A to set priorities for technical assistance for regional policy cooperation in agricultural biotechnology, identify possible partners or programs to complement USAID activities and/or leverage resources, and drafted a three-year proposal for policy support to ASEAN that will be implemented as Activity 12. Further, she helped RDM/A assess ASEAN interest in specific activities to support regional biotechnology policy development.

Activity 13: West Africa Policy Support

Dr. Potter of AGBIOS attended and participated in the Réunion sur le Projet Régional de Biosécurité en Afrique de l’Ouest in Cotonou, Benin, September 21–23, 2006, and produced trip notes.

TECHNICAL CONFERENCES (A.3.6)

Activity 1: APEC Conference on Biosafety Policy Options, Manila, Philippines, January 16 –18, 2006

APEC, in collaboration with the Department of Agriculture of the Republic of the Philippines and USAID, held the APEC Conference on Biosafety Policy Options in Manila, January 16–18, 2006. The primary participants in the conference, which was co-sponsored by the economies of the United States, Philippines, Vietnam, Peru, and Canada, included regulators, government policy makers, and experts in the areas of agriculture, trade, environment, economics, and foreign affairs. The conference focused on exploring policy options for biosafety regulation in the APEC region. The theme of the conference reflected one of the priorities identified in the APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB). Topics covered included comparison of economies' obligations under the World Trade Organization and the Cartagena Protocol, impact of regulation on trade flow in the APEC region, differing impacts and implications for importing and exporting countries, biosafety regulation and socioeconomic considerations, regional initiatives for biosafety compliance, impact of biosafety regulation on public-private research in agricultural biotechnology, and economy experiences of biosafety policy development and implementation. The specific aims of the conference were to give participants a clearer understanding of the breadth of sectoral considerations embedded in biosafety policy, and to increase their understanding of the implications and options for agricultural biotechnology regulation in different sectors of government. In the longer term, it is hoped that, based on this increased understanding and sharing of experiences, APEC economies will be able to successfully meet the requirements of international agreements, thus strengthening their agricultural biotechnology sectors.

TRADE CAPACITY BUILDING (A.3.7)

No activities under A.3.7 during Year 1.

YEAR 2: OCTOBER 2006–SEPTEMBER 2007 (RECAP)

BIO-ENGINEERED COTTON IN AFRICA (A.3.2)

Activity 15: Burkina Faso Cotton Stakeholders Workshop—October 29–31, 2007

Genetically engineered cotton is spreading in spite of the fact that many governments are reluctant to approve commercial production. While the technology has great potential, there are genuine concerns about it. If the sub-region is to benefit quickly from modern biotechnology tools and products in a safe environment, some of the specialized services may be more effectively addressed at the sub-regional rather than the country level in order to maximize the use of both human and material resources. Tackling biosafety issues at a sub-regional level is also logical: technologies and GM plants will informally be able to cross national borders; therefore, risk assessments and legislations of different nations must consider practices and biodiversity present in neighboring countries. This activity, set-up by ICAC and DAI, entailed a three-day workshop in Burkina Faso that focused on the above issues and allowed the sharing of experiences from other countries, particularly developing countries. The workshop promoted direct, open discussions with government authorities responsible for making decisions on the issue in the region. The stakeholder workshop had the following specific objectives: 1) provide an open platform for discussion on biotech cotton; 2) facilitate a better understanding of a science-based regulatory system and provide better understanding of patents and intellectual property protection law; and 3) examine West African small-scale farmers' expectations from biotech cotton and identify major constraints and

challenges that must be addressed for the ultimate benefit of small-scale cotton farmers. Participants included key policy makers, development and donor agencies, research scientists, representatives of farmers' associations, and members of the cotton chain. Representatives of the private sector involved in biotech issues and recognized international experts from outside the region discussed selected topics. The workshop did not have an advocacy role, but instead promoted the sharing of information.

REGULATORY ASSISTANCE (A.3.3)

Activity 9.3: Burkina Faso Field Trials Training

This activity was conducted at the request of the National Biosecurity Agency (ANB) of the Ministry of Environment in Burkina Faso and provided technical assistance to strengthen its risk assessment and risk management capability with respect to environmental releases of transgenic plants in agriculture. A workplan of training activities was developed in consultation with the National Biosecurity Agency in August 2006 (Activity 9.2). The activity was executed by AGBIOS and focused on a training workshop (November 27–December 2, 2006) on the regulation and risk management of confined field trials, which provided the following: 1) a review of the relevant information requirements for applications for experimental confined field trials and resulted in the elaboration of the “formulaire de demande d’essai de recherche au champ en conditions confinées” (application form); 2) a training for ANB staff on risk assessment and compliance management of confined field trials; 3) the development of general and specific terms and conditions of authorization; 4) the development of crop-specific inspection and monitoring standards and procedures; and 5) a Bt cotton field trial visit.

Activity 21.1: Technical Assistance on the Cotton CRC Meeting—Jaffe

USAID supports an initiative by INSAH to develop a regional biosafety framework for West Africa. INSAH hosted the inaugural meeting of the Regional Consultative Committee (CRC) on July 17–19, 2007. The CRC is the body through which the regional biosafety convention will be developed and approved. CRC delegates will carry recommendations and outcomes of the meeting back to their respective countries for approval. USAID supported the travel of a biosafety and biotechnology expert (Dr. Gregory Jaffe, Director, Biotechnology Project, Center for Science in the Public Interest) to attend the CRC meeting in Bamako, Mali. In particular, the expert presented the World Bank-WAEMU regional biosafety project to the meeting participants and led discussions on how the current INSAH initiative can be coordinated with the WAEMU project.

TECHNICAL ASSISTANCE TO FOOD AID RECIPIENT COUNTRIES (A.3.4)

Activity 6: Economic Analysis to Support Priority Setting for Investment in Ag-Biotech West Africa

DAI has issued a fixed-price purchase order to Dr. Jeremy Foltz to perform an economic analysis to support priority setting for investment in agricultural biotechnology for West Africa. Using a model of regional agricultural production and markets developed by the International Food Policy Research Institute (IFPRI) that can be used to generate impact estimates for agricultural technologies in general, Dr. Foltz has analyzed the potential impact of specific agricultural biotechnologies for West Africa.

Activity 12.2: Vietnam Field Trials Workshop

Pursuant to RDM/A's goal of supporting regional biotechnology policy development, DAI's implementing partner AGBIOS organized a conference in Vietnam on field trial compliance for delegates from ASEAN countries.

Activity 23: Brochure Translation

This activity entailed the translation (into French) and reproduction (at 1,200 units) of a USAID brochure titled *Agricultural Biotechnology for Development*.

BIOSAFETY POLICY AND REGULATORY ASSISTANCE (A.3.5)

Activity 16: Kenya Safety Bill—Outreach to Parliamentarians

The need to enhance parliamentarians' understanding of the technical, legal, environmental, and socioeconomic issues and subsequent implications of a quality and practical regulatory process to guide deployment of biotechnology is critical. Evidence abounds of parliamentarians' low levels of knowledge on the subject and, among a majority, non-appreciation of the important contribution that modern biotechnology could make in the national economy. Excerpts from a motion that debated a ban on GMOs in Kenya last year exposed the high level of ignorance and confusion on matters related to the legal process. And, with a likely tabling of the national draft biosafety bill in Parliament for eventual enactment, the current scenario calls for concerted efforts to correct the situation. The proposed activities aim at addressing this challenge by reaching out to the relevant parliamentary committees and building a strong team of champions to ably defend the bill from a point of knowledge. The activity has three components: 1) lunch meetings with parliamentary committee members; 2) a roundtable with a wider group of parliamentarians; and 3) a workshop in Mwea on KARI's Bt-cotton trials.

Activity 19: Support to the West Africa Regional Biosafety Initiative

USAID continued to support the West Africa Regional Biosafety Initiative and support participation of experts in the upcoming West Africa Ministerial conference through four upcoming activities:

1. Representation of the initiative at the Third Coordination Meeting for Governments and Organizations Implementing of Funding Biosafety Capacity-Building Activities, February 26–28, 2007, Lusaka, Zambia, hosted by the Secretariat to the Convention on Biological Diversity.
2. Participation on the CORAF selection panel for Biotechnology Coordinator position and meetings with CORAF representatives on CORAF biotechnology- and biosafety-related priorities, March 5–9, 2007, Dakar, Senegal. This will also included meetings with the INSAH Biosafety Coordinator and USAID Africa Mission representative to be held in either Dakar or Bamako.
3. Technical assistance in the development of a memorandum of understanding between WAEMU and ECOWAS for cooperation on a unified regional biosafety initiative for West Africa.
4. Technical assistance to West African experts in the development of a background paper and presentation on biosafety for the West Africa Ministerial conference. The representation was provided by Mr. Don MacKenzie of AGBIOS.

Activity 22: Risk Assessment Workshop, Burkina Faso

This was a technical assistance activity at the request of the National Biosecurity Agency of the Ministry of Environment in Burkina Faso to strengthen its risk assessment and risk management capability with respect to pre-market environmental risk assessment for the release of transgenic plants in agriculture. This activity is included in the workplan of training activities that was developed in consultation with the National Biosecurity Agency in August 2006 (Activity 9.2). This second training activity (September 10–13, 2007) was a workshop on the pre-market environmental risk management of Bt cotton, which provided the following: 1) a risk assessment case study based on MON 15985 Bt cotton, which has been part of field trial evaluations in Burkina Faso since 2003; 2) training for ANB staff and specialist scientific advisors on data requirements and risk assessment for pre-market approval of transgenic crops. Executed by AgBios, the activity included: 1) the organization and delivery of a four-day workshop for members of the National Biosecurity Agency, members of the National Biosafety Committee (with representatives from the Ministries of Health, Agriculture, Commerce, and Research) and specialist scientific advisors with expertise needed for pre-market environmental risk assessment for Bt cotton; 2) the preparation of a case study application for MON 15985 based on information available from regulatory agencies and the developers; and 3) the translation into French of the AGBIOS case study on MON 15985 cotton—a valuable resource for the National Biosecurity Agency of Burkina Faso and for regulators and scientists in other Francophone countries in West Africa.

TECHNICAL CONFERENCES (A.3.6)

Activity 7: Kenya Roundtable on Biotech

This activity was cancelled.

Activity 14.3: Burkina Faso Field Visit and Workshop

This International Service for the Acquisition of Agri-biotech Applications (ISAAA)-executed activity focused on a field visit to Bt cotton field trials and a conference in Burkina Faso, which gave cotton stakeholders in the region (Mali, Burkina Faso, Senegal, Benin, and Togo) the opportunity to see and hear about the results of the Bt cotton field trials currently being conducted by INERA. For stakeholders to really understand the technology and the benefits and potential risks of GM crops, there is nothing better than for them to actually see the crops on the ground and to talk to farmers firsthand. These “seeing is believing” activities have proven to be extremely effective in ISAAA outreach activities in Asia and other parts of Africa in demystifying biotechnology, in particular GM crops, for nontechnical stakeholders.

Activity 14.6: Journalist Training, Ghana Ministerial Conference, March 25–30, 2007

The third ECOWAS Ministerial Meeting on Biotechnology took place in Accra, Ghana, March 27–30, 2007. This meeting’s principal objective was to endorse and implement an action plan for the development of biotechnology and biosafety in countries of the ECOWAS. More specifically, the plan aimed to develop biotechnology applications in order to improve agricultural productivity and stimulate competitiveness, while maintaining the natural resource base and creating an enabling environment for this, through the establishment of a sub-regional approach to biosafety and a steering, monitoring, and evaluation committee that would facilitate the implementation of the Plan. With the promotion of responsible deployment of biotechnology in the region as the main thrust of the conference, the meeting attracted some strong reactions from civil society groups. Several nongovernmental organizations—including Consumers International, the Coalition pour la protection du patrimoine genetique au Mali, and

the ‘Reseau des Organisations Paysannes et des Producteurs d’Afrique de l’Ouest’ (ROPPA)—attended the Conference and made their voices heard as they did in Bamako in 2005. It was thus necessary to ensure that correct, balanced, and consistent messages on biotech and biosafety issues were shared with the public through the media. ISAAA facilitated a two-day media training workshop for journalists from the West African region in preparation for the Ministerial Meeting; monitored the nature of biotech media coverage and, where necessary (in cases of gross misinformation), provided timely rejoinders; and provided the international media and other biotech stakeholder organizations present with timely press releases on specific topics and issues covered by the meeting.

Activity 17: ECOWAS Ministerial Meeting on Biosafety, Accra, March 27–30, 2007

The Third ECOWAS Ministerial Conference on Biotechnology and Biosafety was hosted by the Government of Ghana, March 27–30, 2007, in Accra. The overall goal of the conference was to create political momentum to drive the ECOWAS Biotechnology and Biosafety Action Plan and to examine/adjust the plan based on studies and processes that were recently completed. ECOWAS and the Government of Ghana contributed the bulk of the funds while USAID/WA agreed to fill in the remaining gap. The activity entailed providing organizational support to the conference (contracting with local partner FARA, arranging hotel/facility reservations, contracting speakers, translating the paper developed by Dr. Foltz under Activity 6, and delegating a resource person to the conference).

TRADE CAPACITY BUILDING (A.3.7)

Activity 12: Biotech Policy, ASEAN Nations

This activity was cancelled [but picked up again in the last quarter of 2008].

YEAR 3: OCTOBER 2007–SEPTEMBER 2008

BIO-ENGINEERED COTTON IN AFRICA (A.3.2)

Activity 18: Cotton Breeder Training Project

The objective of this activity was to provide training to West African cotton breeders from cotton-4 (C4) countries. The program took on the form of a six-month program at two universities, New Mexico State University and the University of Arkansas, in advanced molecular breeding techniques. Cotton is an economic mainstay in West Africa, generating a major share of the exports in several countries and contributing to the livelihoods of significant numbers of people in farming and related sectors. Under the USAID West African Cotton Improvement Program, the U.S. Government is meeting its commitments to the C4 countries (Benin, Burkina Faso, Chad, and Mali) by providing assistance to the cotton sector—in part through improving yields and incomes of cotton producers. There is limited scientific capacity in these countries, however, to use transgenic materials in breeding programs or to carry out advanced breeding activities. USAID was therefore seeking to provide short-term technical training to West African cotton breeders in order to build national capacity in molecular breeding techniques. The countries and NARS institutes included here are Benin (Institut National des Recherches Agricoles du Benin—INRAB), Burkina Faso (Institut National pour l’Environnement et al Recherche Agricole—INERA), Chad (Institut Tchadien de Recherche Agronomique pour le Développement—ITRAD), Mali (Institut d’Economie Rurale—IER). Under separate funding, a fifth candidate from Malawi was added to the group. All five trainees successfully completed the program.

REGULATORY ASSISTANCE (A.3.3)

Activity 21.2: Technical Assistance on the Inaugural Cotton CRC meeting, July 17–19, 2007, Bamako, Mali

USAID supported an initiative by INSAH to develop a regional biosafety framework for West Africa. INSAH hosted the inaugural meeting of the Regional Consultative Committee on July 17–19, 2007. Consisting of delegates from ECOWAS and CILSS countries, the CRC will form working groups to define its role and procedures. The CRC is the body through which the regional biosafety convention will be developed and approved. CRC delegates will carry recommendations and outcomes of the meeting back to their respective countries for approval. INSAH has requested assistance in developing the program and moderating this meeting. AGBIOS will provide this assistance. INSAH will propose to the CRC that it commissions a study on the health and environmental safety of Bt cotton. The study would convene a regional panel of qualified scientific experts to form a consensus assessment of the safety of Bt cotton. INSAH has requested support in formulating this suggestion to the CRC delegates, and in providing technical assistance and guidance to the study panel. Tasks in this activity included identifying delegates, presenters, and participants; developing an agenda; preparing background materials; outlining expectations and procedures; moderating discussions; providing guidance on next steps in the organization plan and in the creation a regulatory framework; describing experiences gained in other countries/situations having relevance to the current process; presenting background information on the functioning of other biosafety frameworks; and assisting with presenting to the CRC delegates the suggestion to convene a study panel on the environmental and health safety risks of Bt cotton.

For the first part of Activity 21.2, the meeting enabled consultation with environmental departments of ECOWAS countries and the delegates were broadly accepting of the CILSS Convention on Biosafety. One criticism of the INSAH-CILSS process has been that it was developed by ministries of agriculture and did not include national biosafety focal points or ministries of environment. This workshop and the proposed further consultation on the revised convention will help negate this criticism. The workshop delegates were positive toward the CILSS Convention, seeing it more as a standards-setting and information-sharing process than a decision-making or review process. It seems likely that the revised CILSS Convention on Biosafety will be adopted by ECOWAS and that the CRC will receive all national decisions, formulate rulings on marketing of approved transgenic organisms in the region, and set regional technical standards and processes. However, ECOWAS has no funding to implement the framework. Unless pressure is put on UEMOA to consider the CILSS-ECOWAS convention in their development of a regional framework, they may develop a second regional framework. Their access to funding gives them quite a bit of power, but they would have a limited regional mandate. Alternatively, if a UEMOA regional framework gives more responsibility to the regional committee, then it could be a better process, as the CILSS-ECOWAS CRC has been stripped of most decision-making and reviewing responsibility. However, the regional players do not believe that Burkina Faso will opt for regional decision making because they are set up to make national decisions.

The second part of Activity 21.2 was a biosafety review of Bt cotton by the CRC subcommittee on biosafety. This no longer fits the priorities of INSAH, which has been tasked with finalizing the CILSS-ECOWAS Biosafety Convention and the CRC Structures and Functions documents for circulation to all ECOWAS focal points and then submission to ECOWAS. The participants set a tight timeframe for this process, requesting the revised documents by the end of August 2007, comments returned by the end of September, and submission of the final documents to ECOWAS by the end of the year for signing in early 2008.

Activity 24: Technical Support to INSAH—ECOWAS Biosafety Regulation 1

As part of USAID's support to an initiative by INSAH to develop a regional biosafety framework for West Africa, INSAH hosted a consultation meeting of delegates from ECOWAS and CILSS countries in July 2007 and received a mandate to modify the CILSS Biosafety Convention and prepare an ECOWAS biosafety regulation. INSAH has requested assistance in modifying and developing these documents. AGBIOS was subcontracted to provide technical assistance to INSAH to modify the INSAH-CILSS convention document according to the recommendations of the working groups and to draft the ECOWAS biosafety regulation. AGBIOS reviewed the proposed changes, suggested structural changes to meet these proposals, and reviewed the requirements for ECOWAS regulations. To facilitate this process, Dr. Siaka Dembélé, INSAH biosafety coordinator, traveled to Canada November 19–30 to work on developing the convention and regulation documents with AGBIOS staff. INSAH circulated the revised document to the country representatives who attended the meeting, processed the feedback, and submitted the final version to ECOWAS.

Activity 25: Technical Support to INSAH—ECOWAS Biosafety Regulation 2

INSAH requested assistance in developing and reviewing the technical annexes to the Biosafety Convention. AGBIOS was subcontracted to provide technical assistance to INSAH in preparing drafts (English and French translations) of the technical annexes and participated in a meeting of regional experts to review and finalize the annexes. This meeting took place on March 18–21, 2008 in Bamako. The activity also entailed continued coordination with Dr. S. Dembélé on the finalization of the Biosafety Convention annexes and preparation of a revised document for presentation to ECOWAS.

The meeting was successful in achieving its goal of agreement at the technical level. Apart from the organizational changes required in combining the two documents dealing with confined field trials into a single annex, many of the adopted changes were aimed at improving the understandability of the documents. There were no significant changes proposed that would affect the overall risk assessment/risk management approaches embodied in the drafts provided for review. As they stand, the technical annexes represent a rational risk-based approach to dealing with the three most pressing issues for the CILSS region: field trials of GM plants, unconfined (or commercial) release, and GM imports for use in food (i.e., food aid), feed, or processing. The data requirements for risk evaluation and the risk management procedures (for field trials) are consistent with internationally accepted practices. In particular, the simplified (or accelerated) approach to dealing with commodity imports for direct use (i.e., LMO-FFPs; Annex 3) could offer countries in the region a practical solution to dealing with a real and pressing concern.

During the last day of the meeting, there was a general discussion on some of the articles in the CILSS Biosafety Convention, particularly those that dealt with the division of responsibility and decision-making authority between national bodies and the proposed regional structure (Regional Biosafety Committee). This will be a critical point to resolve quickly because it affects not only the overall value and effectiveness of this regional coordination mechanism but also its acceptability to countries in the region.

TECHNICAL ASSISTANCE TO FOOD AID RECIPIENT COUNTRIES (A.3.4)

Activity 14.1: Activities with RECOAB and the Media

This activity focused on the further strengthening and training of RECOAB (Réseau des Communicateurs Ouest Africains sur la Biotechnologie Agricole). In Sub-Saharan Africa, the mass media remain the major source of information on agricultural biotechnology. Surveys conducted in East and South Africa (ABSF/ISAAA 2004; AfricaBio 2005) have found that over 60 percent of stakeholders obtain biotech information from the mass media. However, despite their acknowledged role, mass media in Africa appear unprepared to handle the complex issues involved from a balanced perspective. Ironically, even policy makers and majority politicians rely heavily on the information they obtain from the media. Implementation of a strong regional communication strategy has remained sporadic, leaving a large proportion of the public highly vulnerable to manipulation by strong anti-biotechnology lobbyists. To address the communication challenge, ISAAA worked very closely with other stakeholders in the region to strengthen the media's role in biotechnology awareness creation. Under these capacity-building activities, journalists developed competencies in the area of biotechnology and were helped to build a body of credible network of contacts on the subject. Proposed activities included: 1) a two-day biotech sensitization workshop for media professionals (including rural radio and TV) in the local languages in Mali and/or Burkina Faso; 2) radio and TV plugs on biotech in the local languages in Mali and Burkina Faso; and 3) media activities surrounding the launch of the ISAAA Annual Review of Biotech Crops.

Activity 14.2: Regular Biotech Briefings with Policy Makers, Media, Farmer Groups, Etc.

For the success and realization of the benefits of biotechnology in Africa, (and indeed globally), acceptance and positive attitudes among consumers will have to be cultivated. There is therefore a need to engage a wide range of stakeholders on a regular basis to capture the concerns and to develop rapid response mechanisms to these issues. Of particular significance among this stakeholder constituency are politicians and parliamentarians who, like the mass media, command a very large audience and whose public pronouncements shape opinions and policies. This is particularly important since the majority of countries are still in the process of developing policies and drafting biosafety guidelines and regulations for presentation and debate in parliament in readiness for enactment into laws. To meet these new challenges, ISAAA continued not only strengthening the ongoing acceptance and capacity-building activities in the region but also performing more interactive work targeted to key opinion leaders such as politicians, parliamentarians, regulatory agencies, seed traders, and farmer-service provider groups. This activity included study tours, the production and distribution of handout materials, and a biotech speaker program.

Activity 14.4: Translation, Production, and Dissemination of Information and Educational Materials

This ISAAA-executed activity focused on an informational campaign that involved the translation, production, and dissemination of information and educational materials and ISAAA key publications (e.g., Pocket K, Annual Review of Biotech Crops).

Activity 14.5–14.7: Support for the Burkina Biotech Association and the ISAAA's Mali Information Node

ISAAA, which executed this activity, has worked with the Burkina Biotech Association (BBA) and the Institut d'Economie Rurale since 2003 in disseminating information and materials to local stakeholders, and worked with them closely during the last Ministerial Meeting held in Mali. Together, they planned press conferences and a communication training workshop for scientists. BBA is an organization of

biotech stakeholders from both the private and public sectors in the country whose mission is, among others, to assist in raising awareness and understanding of biotechnology, in particular genetically modified organisms, among the general public. It is the first of its kind in the sub-region and is headed by Professor Alassane Sere, a former minister (Animal Resources) in the Burkina cabinet and a veterinarian by training. IER is the largest of the national research institutions for agricultural research in Mali. The activity entailed mailing list distribution in Burkina Faso and Mali, and networking with key decision makers (politicians, farmer leaders, extension workers, local private sector, etc.). Activity 14.7 was composed of the ISAAA management activities related to implementing 14.1, 2, 4, and 5.

BIOSAFETY POLICY AND REGULATORY ASSISTANCE (A.3.5)

Activity 8.3: RDM/A Policy Support #2 (Vietnam)

This activity supported USAID/RDM/A in the development of a regional biotechnology policy in Southeast Asia to further the overlapping goals of environmental protection, trade facilitation, and agricultural development. Regional cooperation on biotechnology policy could be facilitated by either promoting collaboration with the ASEAN on a regional program, or focusing on selected countries where it is possible to complement Mission and/or leverage resources. AGBIOS 1) developed an alternative proposal for a two- to three-year ASEAN pilot program with Vietnam and one other ASEAN country, which was submitted to EGAT and RDM/A for presentation at the U.S.-ASEAN information coordination meeting (April 2–3, 2007); 2) held consultations with Vietnamese officials to draft a two-year program of work aimed at moving biosafety regulatory development forward in Vietnam; and 3) by May 31, 2007, submitted to EGAT and RDM/A a two- to three-year program of work for a phased pilot program in two countries that will include options and an approach to identifying a second ASEAN pilot country and for outreach to ASEAN to build support for regional biosafety regulatory discussions at the pilot project's conclusion.

The activity resulted in updated, regional guidelines for the safety assessment of foods derived from GM plants for the environmental risk assessment of GM plants used in agriculture. These can be used by national regulators in ASEAN member states to provide internationally consistent, science-based guidance to product developers/importers. The guidelines may also serve to initiate an ASEAN policy dialogue on approaches to harmonizing product-specific decision making at the regional level.

TECHNICAL CONFERENCES (A.3.6)

Activity 20: APEC Workshop on Liability and Redress, Japan, February 2008

At the January 2007 meeting, the APEC HLPDAB approved a workshop addressing issues surrounding article 27 of the Cartagena Protocol on Biosafety, dealing with Liability and Redress. Enthusiasm for this activity by APEC member economies followed in part from the positive feedback received at the January 2006 APEC workshop on Biosafety Policy Options sponsored by the U.S. Government and the Government of the Philippines. The U.S. Government considered this a timely opportunity to educate, engage, and possibly influence APEC economies, particularly the developing economies, before the next meeting of the parties to the Protocol.

The Second APEC Workshop on Liability and Redress under the Biosafety Protocol was held in Tokyo, Japan, February 13–14 2008. USAID was the lead U.S. Government agency, but worked closely with other U.S. Government agencies, most notably the Department of Agriculture-Foreign Agricultural

Service and the State Department, and solicited input from the industry to develop the agenda for the workshop. The organization was managed by DAI. The workshop began with a welcome reception that was opened by an official from Japan's Ministry of Agriculture and welcome remarks by M. Saigo, Director, Environment and Biomass Policy Division, MAFF; and D. Berman, Minister-Counselor for Agriculture, U.S. Embassy, Tokyo. The status of the Liability and Redress was summarized by R. Lefeber (Netherlands). The presentations were organized along two themes—Implications for the Private Sector and Implications for the Public Sector—and were presented by speakers from China, the United States, the Philippines, Malaysia, and Japan. The workshop closed with working group discussions on the issues and upcoming negotiations to be tackled at the next Cartagena Meeting. Overall, more than 56 people attended (32 from abroad). The workshop was considered a success, as indicated by the participant survey conducted at its end.

TRADE CAPACITY BUILDING (A.3.7)

No activities under A.3.7 during Year 3.

YEAR 4: OCTOBER 2008–SEPTEMBER 2009

BIO-ENGINEERED COTTON IN AFRICA (A.3.2)

No activities under A.3.2 during Year 4.

REGULATORY ASSISTANCE (A.3.3)

Activity 9.1: Bt Cotton Pollen-Mediated Gene Flow Study

Under this activity, AGBIOS addressed the potential pollen-mediated gene flow from Bt cotton to conventional cotton and near-cotton relatives in Burkina Faso. Pollen-mediated gene flow was considered in two agronomic settings typical of cotton production in West Africa. The testing took place using local cotton varieties into which the insect-resistance trait has been introgressed by traditional cross-breeding. The trials involved scientists from INERA, which build experience in this institution, and the information gained from the pollen flow study was directly applicable to the evaluation of Bt cotton in Burkina Faso as well as other regions of West Africa where similar cotton varieties are grown. An important downstream component of this activity was information sharing and communication with other scientists and stakeholders in the region.

Activity 26: Technical Assistance to INSAH on the ECOWAS Regulation on Biosafety

Building on USAID's support to INSAH for the development of a regional biosafety framework in West Africa, this initiative extended the CILSS Biosafety Convention under the ECOWAS mandate. Specifically, it facilitated: (1) the development of an ECOWAS regulation governing the importation, development, manufacture, use of genetically engineered organisms, and products derived thereof, within ECOWAS member states; and (2) a consultative process leading to the adoption of the regulation. The ECOWAS Biosafety Regulation would be consistent with the spirit of the CILSS Biosafety Convention, incorporating the best elements of that framework, including its technical guidance on risk assessment procedures.

Specifically, the activity entailed a **three-day training workshop** on Environmental Risk Assessment of Transgenic Crops, convened by INSAH, and to continue development of the draft ECOWAS regulation on risk assessment. This workshop was held by ECOWAS and INSAH/CILSS in Bamako from 1-3 December 2008. The workshop was attended by 23 national representatives from 13 West African countries (Chad was included as a CILSS member, although not an ECOWAS Member State) representing the national focal points from these countries together with participants from ECOWAS and INSAH. The workshop content was prepared by AGBIOS and presented by two external facilitators. The format of the workshop, with workbook sessions handled in small groups, allowed for extensive discussions among the participants and with the facilitators.

As a follow-on to the meeting in Ghana in August to **draft a regulation for ECOWAS** on common elements for risk assessment of transgenic plants, a small group met at INSAH in Bamako on 4-5 December to address the issues raised at the Ghana meeting. The group comprised of members from INSAH/CILSS, ECOWAS and the national representative from Nigeria. In addition to discussion on the role of the regional competent authority, a second convention was drafted covering the establishment and functioning of this regional authority, named West African Biosafety Committee (COAB/WABCo) with a membership of one representative from each of the ECOWAS Member States, plus Mauritania and Chad.

TECHNICAL ASSISTANCE TO FOOD AID RECIPIENT COUNTRIES (A.3.4)

No activities under A.3.4 during Year 4.

BIOSAFETY POLICY AND REGULATORY ASSISTANCE (A.3.5)

Activity 10.1: Biosafety Review of Field Trials

USAID has instituted procedures to assess and manage potential negative effects of USAID funded research involving recombinant DNA technology on the environment, agriculture, and human health which might arise from the testing of bioengineered organisms in developing countries. In accordance with this, a submission to address USAID policy biosafety proposal and reporting requirements for confined field trials of pod borer resistant cowpea in Nigeria was evaluated by three external reviewers. The external reviews are provided below and the reviewers have identified where additional information or clarification of the information provided in the submission is recommended. The subject of this review is genetically engineered cowpea that is resistant to the Maruca pod borer. No evidence was found to suggest that, if properly conducted, this field trial of genetically engineered cowpea will present an additional risk to the environment, biological diversity or human or animal health. It is thus recommended that this activity be approved. However, as an added measure it is also recommended that a third party audit of trial activities be conducted to ensure that procedures are being implemented as planned. This activity was led by Dr. MacLean of AGBIOS.

Activity 10.2: Coordination of Review Activities for Commercial Release

As is required of all US federal agencies under Regulation 216, USAID must conduct environmental reviews of all activities to ensure there are no significant environmental impacts. USAID policy with respect to biotechnology projects elaborates specific procedures with respect to open releases of bioengineered organisms. To ensure a strong and technically sound review, those procedures include

soliciting external reviews. This scope of work is to assist USAID with managing the external review process, specifically for genetically modified varieties of potato (South Africa), cotton (Uganda), and eggplant (India). The reviews, done from Canada by AGBIOS, found that there were some deficiencies that needed to be addressed.

TECHNICAL CONFERENCES (A.3.6)

No activities under A.3.6 during Year 4.

TRADE CAPACITY BUILDING (A.3.7)

Activity 12.1 - APEC Technical Assistance #1

USAID's increased investment in agricultural biotechnology, strategically distributed in Asia as well as in other parts of the world, recognizes not only the importance of agricultural growth and productivity in general for developing countries, but more specifically the importance of adoption of new technologies, such as in agriculture for such countries. USAID/RDM/A and EGAT/ESDP/IRB, working through the APEC HLPDAB, seek to support regional biotechnology policy development in Southeast Asia to further the overlapping goals of environmental protection, trade facilitation, and agricultural development. At the seventh meeting of the HLPDAB in February 2008, a main issue of discussion was commodity trade and the low-level presence in food of recombinant DNA plant materials that have been authorized in one or more countries but not in the country of import. Reflecting the keen interest many APEC economies had in the issue of low-level presence, there was a recommendation for the Policy Dialogue to undertake work on harmonization of scientific approaches to low-level presence. The recently adopted low-level presence Annex (LLP Annex) to the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants provides recommendations on performing a food safety assessment of a biotech product when the product only appears at low levels and has passed a food safety assessment by another country according to the Codex Guideline. The LLP Annex does not give guidance on what defines "low levels" of a product, nor does it give guidance on how countries should undertake risk management subsequent to a risk assessment.

Now that the Codex Annex on LLP has been adopted, the U.S. Government considers that it would be useful for economies to analyze their domestic regulatory systems to see how well these systems can benefit from the use of the Annex. The use of the new LLP Annex would provide economies with an important tool to help facilitate trade in agricultural biotech products. This activity entailed organizing the first of a series of APEC roundtable discussions complementary to and non-duplicative of those in other fora in which economies: 1) share information on their domestic regulations, in particular with reference to how the Annex might be used within their regulatory systems, and how those systems align with use of the Annex; 2) discuss economic and trade implications of alignment of the regulatory policies of APEC economies with the Annex; and 3) discuss creative solutions used in non-biotech regulatory contexts to see if they could be applied to address biotech trade issues related to low-level presence of unauthorized rDNA plant materials in food. The workshop took place in Singapore on February 17-18, 2009 and was led by Dr. Julian Adams of USAID.

Activity 12.3 - APEC Technical Assistance #2

This activity, implemented by DAI, with Iowa State University (ISU) and Asia Biobusiness (ABB) as its technical and logistical partners, entails a follow-up workshop to the one conducted under 12.1. This second workshop is titled *LLP Case Study Review and Introduction to Process Management*, and the objectives were to review case studies of existing experiences with the LLP Annex and to introduce the process management methodology to the LLP working group. Four case studies were selected among the APEC economies and presented and analyzed in detail as per agreement of the Steering Committee. The selection featured economies at widely varying ends of the spectrum (Canada, the Philippines, Australia, Argentina). In addition, Iowa State University staff prepared and facilitated an introductory presentation on process management principles, development, and structure for the APEC Economies. In this context, a draft, adapted “Food Safety Process Management Manual” was developed to reflect the LLP Annex content. A total of 30 participants from 14 APEC Economies participated in this second workshop which took place in Singapore on July 13-14, 2009. APEC Economies represented included Australia, Canada, Chile, China, Chinese-Taipei, Indonesia, Malaysia, Peru, Philippines, Russia, Singapore, Thailand, USA, and Vietnam.

ONGOING ACTIVITIES

[EXTENSION PERIOD YEAR 5 OCTOBER 2009–SEPTEMBER 2010]

BIO-ENGINEERED COTTON IN AFRICA (A.3.2)

Possible continuation of activity 18, cotton breeders training.

REGULATORY ASSISTANCE (A.3.3)

No ongoing activities under A.3.3.

TECHNICAL ASSISTANCE TO FOOD AID RECIPIENT COUNTRIES (A.3.4)

No ongoing activities under A.3.4.

BIOSAFETY POLICY AND REGULATORY ASSISTANCE (A.3.5)

No ongoing activities under A.3.5.

TECHNICAL CONFERENCES (A.3.6)

No ongoing activities under A.3.6.

TRADE CAPACITY BUILDING (A.3.7)

To be specified continuation of APEC Technical Support Activities.

ANNEX A: CONTRACT DELIVERABLES COMPLETED/IN PROGRESS

Deliverables		Number of Deliverables Completed as of September 2009	Year 1: October 2005–September 2006 (Completed Activities)	Year 2: October 2006–September 2007 (Completed Activities)	Year 3: October 2007–September 2008 (Completed Activities)	Extension Period: October 2008–September 2010 (Ongoing Activities)
1.	5 study tours related the following tasks: cotton, regulation of biotechnology; and regulation of imports such as food aid;	1	<i>Activity 13: West Africa Policy Support</i>			
2.	11 technical conferences, related to the following tasks: cotton, food aid, regulation of biotechnology, trade capacity building, and regional policy dialogs;	8	<i>Activity 1: APEC Conference</i>	<i>Activity 12.2: Viet Nam Field Trials Workshop</i> <i>Activity 15: Burkina Faso Cotton Workshop</i> <i>Activity 12.2: Viet Nam Field Trials Workshop</i> <i>Activity 22: Risk Assessment Workshop Burkina Faso</i> <i>Activity 14.3: Burkina Faso Field Visit and Workshop</i> <i>Activity 17: ECOWAS Ministerial Meeting on Biosafety wGhana</i>	<i>Activity 20: APEC Workshop Japan</i>	

Deliverables		Number of Deliverables Completed as of September 2009	Year 1: October 2005–September 2006 (Completed Activities)	Year 2: October 2006–September 2007 (Completed Activities)	Year 3: October 2007–September 2008 (Completed Activities)	Extension Period: October 2008–September 2010 (Ongoing Activities)
3.	3 short-term training programs on breeding of biotechnology crops or management of insect resistance in biotech cotton;	3	<i>Activity 2: Entomology Training</i>	Activity 9.3 Burkina Faso Field Trials Training	<i>Activity 18: Cotton Breeders Training</i>	
4.	Technical assistance to up to 10 countries in regulatory aspects of biotechnology (related to cotton, food aid, or adoption of biotechnology crops), including road maps for regulatory development, guidelines, and training.	24	<i>Activity 3: INSAH/CILLS Technical Support</i> <i>Activity 4: Translation of ECOWAS action plan</i> <i>Activity 5: INSAH Technical Support 2</i> <i>Activity 9.2 Technical Assistance to Burkina Faso</i> <i>Activity 11: INSAH Convention Translations</i>	Activity 10.1: <i>Biosafety Review of Field Trials</i> <i>Activity 10.2: Coordination of Review Activities for Commercial Release</i> <i>Activity 21.1: TA to Cotton CRC Meeting</i> Activity 16: Kenya Safety Bill Outreach Activity 19: Support to WA Regional Biosafety Initiative Activity 14.6: Journalist training Ghana Ministerial Conference	<i>Activity 21.2: Technical Assistance on the CRC Meeting</i> <i>Activity 14.1: Activities with RECOAB and the Media</i> <i>Activity 14.2: Regular Briefings with Policy Makers, Media, Farmer Groups, etc.</i> <i>Activity 14.5: Support to Burkina Biotech Association and Mali Information Node</i> <i>Activity 8.3: RDMA Policy Support #2</i> <i>Activity 24: Technical Support to INSAH—ECOWAS Biosafety Regulation 1</i> <i>Activity 25: Technical Support to INSAH—ECOWAS Biosafety Regulation 2</i>	<i>Activity 9.1 Bt Cotton pollen-mediated gene flow study</i> <i>Activity 10.1: Biosafety Review of Field Trials</i> <i>Activity 10.2: Coordination of Review Activities for Commercial Release</i> <i>Activities 12.1: APEC Technical Assistance on LLP #1</i> <i>Activities 12.3: APEC Technical Assistance on LLP #2</i> <i>Activity 26: Technical Assistance to INSAH on the ECOWAS Regulation on Biosafety</i>

Deliverables		Number of Deliverables Completed as of September 2009	Year 1: October 2005–September 2006 (Completed Activities)	Year 2: October 2006–September 2007 (Completed Activities)	Year 3: October 2007–September 2008 (Completed Activities)	Extension Period: October 2008–September 2010 (Ongoing Activities)
5.	Briefing papers related to the following tasks: food aid, regional policy dialogs, trade capacity building, and regulatory assistance.	3		<i>Activity 6: Economic Analysis to Support Priority Setting for Investment in Agricultural Biotechnology for West Africa</i> <i>Activity 23: Brochure Translation</i>	<i>Activity 14.4: Translation, Production and Dissemination of information materials</i>	
6.	Curriculum for 2 USAID and USG training courses in biotechnology.	2	<i>Activity 8.1: RDMA Policy Support</i> <i>Activity 8.2: RDMA Policy Support # 2</i>			
7.	Progress reports.	5	<i>Oct 2005–Feb 2006</i> <i>Mar 2006–Sep 2006</i>	<i>Oct 2006–Sep 2007</i>	<i>Oct 2007–Sep 2008</i>	<i>Oct 2008–Sep 2009</i>